

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ALL CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

MOTION FOR ORDER REQUIRING PRESERVATION OF EXPLANTED MESH

This MDL concerns claims that Ethicon mesh implanted in women for the treatment of pelvic organ prolapse and stress urinary incontinence is defective or that Ethicon did not properly warn of the risks of that mesh. The mesh itself is probably the most important piece of evidence in each case, as the parties need the explanted mesh for appropriate pathology analysis as well as to determine whether the physical characteristics of the mesh changed after implantation.

Over the course of this litigation, the parties have endeavored (unsuccessfully) to form a protocol for the preservation of mesh explanted from plaintiffs in this MDL. These efforts have floundered in the details. Meanwhile, explantation surgeries have taken place and continue to take place, and there are no assurances that a) the specimens will be preserved or b) that Defendants will have proper access to them.

Accordingly, to protect their ability to defend these suits, Defendants request the Court enter an order:

1. Requiring Plaintiffs to advise their healthcare providers of the duty to preserve the explanted mesh material, and the appropriate measures for doing so; and

2. Requiring that Defendants shall be given access to one half of any explanted material in a condition that enables Defendants to do their own testing.

It is the Plaintiffs' duty to preserve this evidence and allow Defendants access to it. The parties have engaged in extensive meet and confers and have been unable to agree about the technical requirements for preservation. Those technical details aside, the primary concern—and what Defendants seek with this motion—is that preservation occur and that the Defendants be given access to the evidence.

ARGUMENT

Plaintiffs cannot seriously contest that they have a duty to preserve the explanted mesh material. They are plaintiffs in this ongoing litigation, and this critical piece of evidence is in their custody or control.

Indeed, the preservation of the allegedly defective product is particularly important in a products liability case such as this. As one treatise has described:

All too frequently, these “crown jewels” are negligently or intentionally lost or significantly altered between the time of the accident and either the time for an opposing counsel or opposing expert to see it, or the trial.

3-18 FRUMER & FRIEDMAN, PRODS. LIAB. § 18.07 (footnotes omitted). Because of the importance of this evidence, numerous courts have recognized the plaintiffs' duty to preserve the allegedly defective product in products cases. *See Silvestri*, 271 F.3d at 591 (holding plaintiff had a duty to preserve vehicle post-accident, even though he was not the owner); *Petry v. La Z-Boy, Inc.*, 2008 U.S. Dist. LEXIS 37873, at *7-8 (S.D.W. Va. May 8, 2008) (Johnston, J.) (holding plaintiffs breached their duty where they “made no effort to contact Defendants to certify that they received notice of access to the recliner or its possible destruction”); *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 29 (Pa. Super. Ct. 2006) (holding that even though it was the

hospital that disposed of the explanted pain treatment device, “responsibility for its preservation remained with the [plaintiffs]”).

The recent *Huskey* and *Edwards* cases only underscore the point. *Huskey v. Ethicon*, Member Case No. 2:12-cv-05201; *Edwards v. Ethicon*, Member Case No. 2:12-cv-09972. In both *Huskey* and *Edwards*, the plaintiffs’ experts (Iakovlev, Guelcher, Pandit and Dunn) offered opinions that the mesh implanted in those women degrades and results in injury. However, in *Huskey*, no one preserved the plaintiff’s explanted mesh, and even though Defendants’ polymer expert could opine generally about the properties of the mesh material and plaintiffs’ experts opinions, he stated in his report that “[b]ecause no explant was available in the *Huskey* litigation, I cannot render scientific opinions as to its condition.” (Thames Report, p. 28, Ex. A). In the *Edwards* case, plaintiffs preserved the mesh explant, but plaintiffs did not give one half to Defendants until *after* the plaintiffs’ expert had performed destructive testing. As Defendants’ expert Shelby Thames concluded:

I have been unable to physically and chemically examine the Tonya Edwards explant due to the destructive and compromising methodology used by plaintiff’s representatives in handling the sample(s). There was no explant distribution or sample splitting made available to the defendants. The entire sample was maintained by plaintiff’s counsel and their experts. The explant sample(s) has been physically and chemically altered irreversibly in such a way that prohibits me from observing, testing, and evaluating the explant in its condition and state at explantation. Accordingly, I cannot [] reach reliable, scientifically valid conclusions via attempting to evaluate the explant in its present state.

(Thames Report, p. 25, Ex. A).¹

Clearly, the condition of the explanted mesh is central to the claims at issue, given Plaintiffs’ allegations that some of the mesh material degrades, frays, and ropes. *Cf. Silvestri*,

¹ In their *Daubert* motions in *Huskey* and *Edwards*, Defendants have moved to exclude certain opinions of plaintiffs’ experts for their failure to test/preserve the mesh.

271 F.3d at 588 (expert noted that a detailed inspection of the vehicle was “critical to performing a crush analysis of the vehicle”).

The threat of destruction of the mesh explants is real and imminent. According to the Manual of Surgical Pathology, the recommended retention times for gross specimens such as these are only 7-14 days after the pathologist’s final report:

TABLE 1-2. RECOMMENDED RETENTION TIMES FOR PATHOLOGY RECORDS AND MATERIALS		
	TJC*	CAP**
Gross specimens	7 days after final report	14 days after final report
Paraffin blocks	At least 2 years	10 years
Slides	10 years	10 years
Cytology slides	5 years	5 years
FNA slides	10 years	10 years
Pathology report	10 years	10 years
<small>*The Joint Commission (TJC) Manual, Appendix E (www.jointcommission.org). **College of American Pathologists Laboratory Accreditation Program Inspection Checklists (www.cap.org).</small>		

See Ex. B. To protect Defendants’ interest in these specimens in defending these claims and avoiding the uncertain destruction of this critical evidence, a preservation order is necessary.

CONCLUSION

For these reasons, Defendants request the Court enter an order (1) requiring Plaintiffs to advise their healthcare providers of the duty to preserve the explanted mesh material, and the appropriate measures for doing so; and (2) requiring that Defendants shall have access to one half of any explanted material in a condition that enables Defendants to do their own testing.

Dated: April 28, 2014

Respectfully submitted,

/s/ Christy D. Jones

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CERTIFICATE OF SERVICE

I hereby certify that on April 28, 2014, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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